

glucose burning, namely heat production, and heat dissipation, the present inventors set up the model disclosed in the paragraph bridging pages 3 and 4 of Applicants' specification. While the presently claimed invention is not limited by the particular features of that model, the apparatus claims do require a measurement portion for obtaining a plurality of measurement values related to a body surface and a measurement environment, including at least a measurement value related to heat measurement. Likewise, the method claims call for the step of obtaining a plurality of measurement values relating to a body surface and a measurement environment, including a measurement value related to heat measurement. The Examiner alleges certain aspects of this measurement to be disclosed by the Cho et al. patent. However, what is clearly not disclosed in the Cho et al. patent and what is a particularly new insight is Applicants' finding that the relationship between the blood glucose level and the amount of heat produced varies between a diabetic patient and an able-bodied person and, accordingly, that this variation should be accounted for in the measuring apparatus and method of the present invention.

Therefore, according to the present invention, the apparatus includes a selecting means for selecting an able-bodied person or a diabetic patient and a calculation portion calculating a blood sugar level based on a plurality of measurement values obtained in the measuring portion and the result of selection by the selecting means. Similarly, the method of the present invention includes the steps of obtaining a type identifying an able-bodied person or a diabetic patient, and calculating a blood sugar level using the obtained plurality of measurement values and a regression function for either able-bodied persons or diabetic patients chosen based on the obtained type identifying an able-bodied person or a diabetic patient. Such is neither disclosed nor suggested by litawaki et al. or Cho et al.

The litawaki et al. patent discloses a blood sugar measuring device to measure blood sugar either noninvasively or with only slight invasiveness. The idea behind the litawaki et al. invention is to input data related to the measurement of blood sugar and use this data as a basis to adjust the calculate the blood sugar value or to prompt the user to redo the measurement. This scheme allows the device of litawaki et al. to compare the measured (actually, estimated) blood sugar values with predicted values resulting from known physiological variables. In predicting the values resulting from known physiological variables, it is disclosed that the time coefficient used in the calculation varies with the severity of the diabetics. However, this information appears to be used only for calculating a predicted value based on the last measured value.

There is no disclosure either in litawaki et al. or Cho et al. that whether the subject is able-bodied person or a diabetic patient should effect the calculation of blood sugar level using at least one measurement value related to heat measurement. Thus, even assuming, arguendo, one of ordinary skill in the art would have substituted the measurement in calculation elements and steps of Cho et al. for those litawaki et al., it is submitted the teachings of these patents would suggest that there would no longer be any need to distinguish between an able-bodied person or a diabetic patient. That is, in litawaki et al., the severity of the diabetes of the subject is used only to predict the blood sugar value, and is not involved with calculating the blood sugar value based on at least a measurement value related to heat measurement.

Accordingly, neither litawaki et al. or Cho et al., nor even the combination thereof, would have suggested a calculation portion for calculating a blood sugar level based on measurement values, including at least a measurement value relating

to heat measurement, and the result of selection by selecting means for selecting able-bodied person or a diabetic person, or a blood sugar level measuring method including calculating a blood sugar level using a plurality of measurement values, including at least a measurement value related to heat measurement, and a regression function for either able-bodied persons or diabetic patients chosen based on the obtained type identifying an able-bodied person or a diabetic patient, as presently claimed.

Accordingly, claims 1, 3, 4 and 10 are patentable over the proposed combination of litawaki et al. and Cho et al.

Claim 2 stands rejected under 35 U.S.C. 103(a) as being unpatentable over litawaki et al. in view of Cho et al. and further in view of U.S. Patent No. 6,322,504 to Kirshner. Applicants traverse this rejection and request reconsideration thereof.

The deficiencies of litawaki et al. and Cho et al. are noted above.

The patent to Kirshner relates to interactive computerized method and system for determining for the risk of developing a disease, consequences of the disease, providing ways of modifying the risk, and tracking the progress of an individual as his or her risk factors change or remain the same. It is disclosed the user's medical history is collected and stored, for example, in a medical history database. For example, the user is queried whether the user has diabetes mellitus and, if so, the user is prompted to enter, if known, his or her blood fasting sugar, whether the user is taking insulin, hypoglycemics or neither insulin nor hypoglycemics. If the user is taking insulin, the user is prompted his or her NPH and/or regular dose. However, there is absolutely no suggestion in Kirshner that this information should be used for measuring blood sugar level. To the contrary, the user is prompted to enter his or her blood fasting sugar. Accordingly, the Kirshner does not remedy any of the

deficiencies noted above with respect to litawaki et al. and Cho et al. Therefore, claim 2 is patentable over the proposed combination of references.

Applicants note the indication of allowable subject matter in claims 5-9 and 11. In view of the foregoing amendments, it is submitted all of the claims now in the application are in condition for allowance.

To the extent necessary, applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to the deposit account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (Case:1021.43510X00), and please credit any excess fees to such deposit account.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Alan E. Schiavelli', is written over a horizontal line.

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